

# 510(k) Summary of Safety and Effectiveness

# **Boston Scientific Corporation**

## iLab<sup>TM</sup> Ultrasound Imaging System

Submitted By

Boston Scientific Corporation

49700 Bayside Parkway

Fremont, CA 94538

**Contact Person** 

Christine Dunbar

Principal Regulatory Affairs Specialist

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christine.dunbar@bsci.com

**Date Prepared** 

September 06, 2007

**Proprietary Name** 

iLab™ Ultrasound Imaging System

Common Name(s)

Ultrasound Diagnostic Imaging System

Ultrasonic Pulsed Doppler Imaging System (90IYN)

Ultrasonic Pulsed Echo Imaging System (90IYO)

Classification

Name(s)

21 CFR Part 892.1550 (90IYN)

Ultrasonic Pulsed Doppler Imaging System

21 CFR Part 892.1560 (90IYO)

Ultrasonic Pulsed Echo Imaging System

Predicate Device The iLab™ Ultrasound Imaging System with software version 1.3 Update and the Integrated Installation Configuration Option is substantially equivalent to the following device:

Product			510(k)	Clearance Date
iLab™	Intravascular	Ultrasound	K051579	July 14, 2005
System				

#### **Description of the Device**

The iLab<sup>TM</sup> Ultrasound Imaging System is designed for real-time viewing of intravascular anatomies and is intended to be a basic diagnostic tool for imaging and evaluation of patients who are candidates for transluminal procedures.

The iLab<sup>TM</sup> System consists of two compact PC units (one for Image Processing and one for Data Acquisition), up to two displays (one primary and an optional secondary). The iLab System imaging and processing PC are used during an intravascular procedure, at the end of the IVUS procedure, the processing PC supports the archiving of the images obtained during the procedure. The iLab System processing PC converts the native iLab images into DICOM format images prior to archiving to removal media such as a CD, DVD or removable hard disk cartridge. Images can also be archived to a DICOM network server.

The iLab<sup>TM</sup> System is available in two configurations: a Cart-based Configuration and an Installed Configuration. There is no functional or electrical difference between the Cart-Based and Installed Configurations; differences are limited to cable lengths and the location of the modules of the system. The main market features of the iLab System are as follows:

#### Cart System

The Cart based system contains the complete iLab System in a portable, compact cart. The Cart System supports one LCD monitor.

#### **Installed System**

Multiple monitor mounting options for installation into the Hospital's catheter lab procedure room

#### **Tableside Controller**

Provides sterile field control of IVUS measurements and playback of IVUS runs

#### Touch Panel

Intuitive user interface and simplified display

#### **Upgradeable**

The iLab system allows for future innovation and technological advancement

The proposed new Integrated Installation Configuration Options supports an additional installed version configuration to enable the use of a customer's existing catherization lab monitor as the second monitor.

#### Intended Use / Indications for Use

The iLab<sup>TM</sup> Ultrasound Imaging System is intended for ultrasound examinations of intravascular pathology. Intravascular ultrasound is indicated in patients who are candidates for transluminal interventional procedures such as angioplasty and atherectomy.

## <u>Device Technology Characteristics and Comparison to Predicate Device</u>

The iLab<sup>TM</sup> System applies ultrasound energy through a transducer enclosed within a catheter. This ultrasound energy is directed from the catheter in the lumen of a vessel into the interior vessel wall of the patient in order to obtain a two-dimensional image of the vessel anatomy. The two-dimensional image, reconstructed from the reflected RF Ultrasound echo, can be used to evaluate the morphology of the vessel and as such potentially detect abnormalities or obstructions. Each of the technological characteristics found in the iLab<sup>TM</sup> System 1.3 Update are identical or similar to those of the predicate device, iLab Intravascular Imaging System,

**Non-Clinical Testing** 

Bench electrical safety and acoustic output safety testing demonstrated that thecurrently

marketed iLab<sup>TM</sup> System, and its accessories met or exceeded performance requirements and is

safe and effective for its intended use.

The Integrated Installation Configuration Option was evaluated by an outside testing agency

for the iLab System and it was determined that no new external testing for EMC was required.

All software risk mitigations determined by the FMEA have been verified to be effective and

demonstrate that the iLab 1.3 Update meets all product and marketing requirements.

Software Verification Testing

Software unit and system level verification testing demonstrate that the 1.3 Update meets the

acceptance criteria as noted in the iLab System Software Unit and System Test Plans. All

requirements in the Software Requirements Specifications have been verified by the system

level testing.

The iLab System 1.3 Update has been fully verified in accordance with applicable FDA

guidance documents. This testing includes software verification testing performed on multiple

configurations of PC systems. The results demonstrate that iLab System 1.3 Update satisfies all

Product and Marketing requirements for its intended purpose as a safe and effective update to

the predicate iLab System.

Software Validation Testing

The iLab System 1.3 Update validation effort will be performed by testers with iLab clinical

experience on PC systems that are production equivalent and meet the minimum system

requirements. The validation results summary report in progress at the time of this submission.

All plans, test results and summary reports will be retained in the Design History File for the

iLab System 1.3 Update project.

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Hardware Verification Testing

The iLab Integrated Installation Configuration Option contains minimal hardware necessary to

send the video signal to the customer's LCD Monitor. The video interface requirements have

been defined, verified and validated to support specified imaging medical device vendors. An

additional on-site validation on 3 or more customer sites who utilize Angiography systems

from these vendors will ensure that the video interface is robust. The use of industry standard

Information Technology Equipment (ITE) certified video converters (also called multi-

modality switches), cabling and monitors provides a broad based video interface for ease in

interconnectivity.

All hardware risk mitigations determined by the FMEA have been verified to be effective and

demonstrate that the iLab Integrated Installation Configuration Option meets all product and

marketing requirements.

On-Site Validation Testing

The on-site validation for the video connections is intended to ensure customer acceptance of

the image quality with the current iLab imaging system when using external video monitors

that meet the video interface requirements. The on-site validation effort is in progress at the

time of this submission.

All plans, test results and summary reports will be retained in the Design History File for the

iLab System Integrated Installation Configuration Option project.

Conclusion

The iLab<sup>TM</sup> Ultrasound Imaging System with the 1.3 Update and the Integrated Installation

Configuration Option, contains the same fundamental technology, has similar technical

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characteristics (i.e. GUI and software functions) and has the same intended use as the predicate device, the  $iLab^{TM}$  Ultrasound Imaging System.

Based on the non-clinical and design verification tests results, the subject device has been shown to be substantially equivalent to the currently marketed device and safe and effective for its intended use..





Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

Ms. Christine Dunbar Principal Regulatory Affairs Specialist Boston Scientific Corporation 47900 Bayside Parkway FREMONT CA 94538

SEP 2 6 2007

Re: K072517

Trade/Device Name: iLab™ Ultrasound Imaging System

Regulation Number: 21 CFR 892.1560

Regulation Name: Ultrasonic pulsed echo imaging system

Regulatory Class: II

Product Code: IYO, ITX and IYO

Dated: September 6, 2006 Received: September 7, 2007

#### Dear Ms. Dunbar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the iLab<sup>TM</sup> Ultrasound Imaging System, as described in your premarket notification:

#### Transducer Model Number

Sonicath<sup>®</sup> Ultra<sup>TM</sup>, 6F 20 MHz Sonicath<sup>®</sup> Ultra<sup>TM</sup>, 9F 9 MHz Sonicath<sup>®</sup> Ultra<sup>TM</sup>, 6F 12.5 MHz Sonicath<sup>®</sup> Ultra<sup>TM</sup>, 3.2F 20 MHz Ultra ICE, 9F 9 MHz Atlanits<sup>®</sup> SR, 3.2F 40 MHz Atlantis<sup>®</sup> PV, 8F 15 MHz
Atlantis<sup>®</sup> SR Pro, 3.2F 40 MHz
Atlantis<sup>®</sup> ICE, 9F 9 MHz
Atlantis<sup>®</sup> SR Pro<sup>2</sup>, 3.2F 40 MHz
iSight, 2.4F 40 MHz

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration Center for Devices and Radiological Health Document Mail Center (HFZ-401) 9200 Corporate Boulevard Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <a href="http://www.fda.gov/cdrh/industry/support/index.html">http://www.fda.gov/cdrh/industry/support/index.html</a>

If you have any questions regarding the content of this letter, please contact Lauren Hefner at (240) 276-3666.

Sincerely yours,

Nancy C. Brogdon

Director, Division of Reproductive, Abdominal and Radiological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure(s)

# **Indications for Use Statement**

510(k) Number:
Device Name: iLab <sup>TM</sup> Ultrasound Imaging System
Indications for Use: The iLab <sup>TM</sup> Ultrasound Imaging System is intended for ultrasound examinations of intravascular pathology. Intravascular ultrasound is indicated in patients who are candidates for transluminal interventional procedures such as angioplasty and atherectomy.
Prescription Use X AND/OR Over-The-Counter Use (Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)  Page 1 of 1  (Division Sign-Off)  Division of Reproductive, Abdominal and
Radiological Devices 510(k) Number

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Division of Reproductive, Abdominal and	Diagnostic Indications for Use Form
Radiological Davison	for the
510(k) Number K072517	iLab <sup>TM</sup> Ultrasound Imaging System

Intended Use: Diagnostic ultrasound imaging of fluid flow analysis of the human body as follows:

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Clinical Application				PWD.	CWD	Color # Doppler	Amplitudes Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic	25451.545	77215676					Committee of the Commit			
Fetal										
Abdominal										
Intraoperative (specify										
Intraoperative Neurological							·			
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal				,						
Transvaginal										
Transurethral										
Intravascular		P								
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial				<u>.</u>						
Other (specify)										
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N = New indication; P = Previously cleared by FDA; E = Added under Appendix E

Additional Comments: Cleared July 14, 2005, K051679

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### Table 5-2: Track 1 Summary Table for the iLab™ Ultrasound Imaging System

Clinical Application	<u>A</u>	В	M	PWD	CWD	CD	Combined (specify)	Other <sup>†</sup> (specify)
Ophthalmic								
Fetal Imaging & Other*	*	<u>x</u>						
Cardiac, Adult & Pediatric					<del></del>		<del></del>	
Peripheral Vessel					***************************************		· ·	
*Abdominal, In	traope	rative, Pe	diatric	, Small (	Organ (b	reast, t	hyroid, testes, o	etc.), Neonatal Cephalic, Adi
Cephalic, Musci								

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<sup>†</sup> Examples may include: Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging

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AV B	N.	PWD	EGWD.	Colors	of Operation Amplitude ADoppler	Entered State of the State of the	Gombined (specify)
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Ophthalmic	Clinical				DVV 140	CHE	CID.	Combined	Other <sup>†</sup>
Examples may include: Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Do	Application	<u>A</u>	В	M	PWD	CWD	CD	(specify)	(specify)
& Other*  Cardiac, Adult & Pediatric  Peripheral Vessel  *Abdominal, Intraoperative, Pediatric, Small Organ (breast, thyroid, testes, etc.), Neonatal Cepter Cephalic, Musculo-skeletal (superficial)  Examples may include: Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Do	Ophthalmic								_
& Pediatric  Peripheral  Vessel  *Abdominal, Intraoperative, Pediatric, Small Organ (breast, thyroid, testes, etc.), Neonatal Cer  Cephalic, Musculo-skeletal (conventional), Musculo-skeletal (superficial)  Examples may include: Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Do	Fetal Imaging & Other*	:	X						_
*Abdominal, Intraoperative, Pediatric, Small Organ (breast, thyroid, testes, etc.), Neonatal Cer Cephalic, Musculo-skeletal (conventional), Musculo-skeletal (superficial)  Examples may include: Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Do	Cardiac, Adult & Pediatric	<del></del>			. <u></u>				_
Cephalic, Musculo-skeletal (conventional), Musculo-skeletal (superficial)  † Examples may include: Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Do	Peripheral Vessel	<del></del>							
	Cephalic, Muse	culo-skel vy includ	letal (con	vention	al), Musc oppler, 3-	ulo-skele D Imagii	tal (sup ng, Har	erficial) ·monic Imaging	g, Tissue Motion De

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,					So	nicath®	Ultra <sup>TM</sup>	1, 9F 9 I	MHz					
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	Peripheral Vascular					<del> </del>			<del></del>					
	Laparoscopic				<del> </del>									
	Musculo-skeletal													-
	Conventional Musculo-skeletal				-									
	Superficial				ļ	_								ļ
	Other (specify)													
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Clinical Application	A	В	M	PWD	CWD	CD	Combined (specify)	Other <sup>†</sup> (specify)
Ophthalmic								<del></del>
Fetal Imaging & Other*		X 				<u></u>		
Cardiac, Adult & Pediatric								_
Peripheral Vessel								_
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Cephalic, Musc	ulo-skele y include	etal (conv	entiona	l), Musc	ulo-skele	tal (sup	erficial)	_
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Division of Reproductive, Abdominal and

Radiological Devices 510(k) Number

K072511

# Diagnostic Indications for Use Form

for the Sonicath® Ultra<sup>TM</sup>, 6F 12.5 MHz

Intended Use: Diagnostic ultrasound imaging of fluid flow analysis of the human body as follows:

Intended Use: Dia	BIIOST	ic uit	14300	na ma			of Operation		roody as to	nows.
Clinical Application	Ä	B	NF.	PWD	cwb	Color Dopplek	Amphilide Doppler	Color Velocity Imaging	Combined (specify)	Otherv (specify)
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Fetal										
Abdominal										
Intraoperative (specify Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic				•	·					
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular		E								
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional Musculo-skeletal Superficial										
Other (specify)										

N = New indication; P = Previously cleared by FDA; E = Added under Appendix E Additional Comments: Released to market February 28, 1997 via Letter-To-File against K902245 (Cleared October 9, 1996).

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Boston Scientific Corporation Special 510(k)

iLab<sup>™</sup> Ultrasound Imaging System, 1.3 Update and Integrated Installation Option

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Clinical Application	<u>A</u>	В	M	PWD	CWD	CD	Combined (specify)	Other <sup>†</sup> (specify)
Ophthalmic						·	· <u> </u>	<del></del>
Fetal Imaging & Other*		X						Merodon
Cardiac, Adult & Pediatric								_
Peripheral Vessel								
Cephalic, Musc	ulo-skele y include	etal (con	vention	al), Musc	ulo-skele	tal (sup	erficial)	etc.), Neonatal Ce
Cephalic, Musc	ulo-skele y include	etal (con	vention	al), Musc	ulo-skele	tal (sup	erficial)	
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Radiological Devices 1072517

**Diagnostic Indications for Use Form** 

for the

Sonicath® Ultra<sup>TM</sup>, 3.2F 20 MHz

Intended Use: Diagnostic ultrasound imaging of fluid flow analysis of the human body as follows:

Intended Use: Dia	ignos	tic ui	traso	una im	aging oi	Huid How	analysis of Operation	the numa	n body as to	ollows:
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Ophthalmic					•					
Fetal										
Abdominal										
Intraoperative (specify Intraoperative										
Neurological										
Pediatric										
Small Organ (specify)								_		
Neonatal Cephalic										
Adult Cephalic					·					
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular		P								
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional Musculo-skeletal Superficial										
Other (specify)										

N = New indication; P = Previously cleared by FDA; E = Added under Appendix E

Additional Comments: Cleared under K970049, June 20, 1997.
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Clinical Application	A	В	M	PWD	CWD	CD	Combined (specify)	Other <sup>†</sup> (specify)
Ophthalmic				·				_
Fetal Imaging & Other*		X	<del> </del>					_
Cardiac, Adult & Pediatric								_
Peripheral Vessel								ndra.

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Diagnostic Indications for Use Form for the

Ultra ICE, 9F 9 MHz

Intended Use: Diagnostic ultrasound imaging of fluid flow analysis of the human body as follows:

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Clinical Application	Ä.	·B	Νī	PWD.	ζŴĎ	Color Doppler	Amplicade s Doppler	Velocity Imaging	Combined (specity)	Ofter (specify)
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Intraoperative (specify										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)					:	!				
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Transurethral										
Intravascular		E								
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional Musculo-skeletal Superficial										
Other (specify)		<u> </u>								

N = New indication; P = Previously cleared by FDA; E = Added under Appendix E

Additional Comments: Released to market December 10, 1997 via Letter-To-File against K902245 (Cleared October 9, 1996).

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Special 510(k)		0.00
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A	В	M	PWD	CWD .	CD	(specify)	(specify)
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	X	<del></del>					_
							_
	aoperativ lo-skeleta	aoperative, Pedia	aoperative, Pediatric, Solo-skeletal (conventional	A B M PWD  X  Aoperative, Pediatric, Small Or lo-skeletal (conventional), Muscuinclude: Amplitude Doppler, 3-I	A B M PWD CWD  X  aoperative, Pediatric, Small Organ (bre lo-skeletal (conventional), Musculo-skeletal include: Amplitude Doppler, 3-D Imaging	aoperative, Pediatric, Small Organ (breast, th lo-skeletal (conventional), Musculo-skeletal (sup-	Combined  A B M PWD CWD CD (specify)  X  aoperative, Pediatric, Small Organ (breast, thyroid, testes, elo-skeletal (conventional), Musculo-skeletal (superficial) include: Amplitude Doppler, 3-D Imaging, Harmonic Imaging,

al Devices 207.			•		for the	for Use Foi ' 40 MHz	'm		
Intended Use: Di	agnostic	e ultra	sound	imaging	of fluid f	low analysi	s of the hi	ıman body	as fol
					Mode	of Operation	la vert		
Ginical Application	a B	VI.	PWD	ewd	Color	Amplitude Doggles	Velouity	Combine (specify)	id.
					a Sulfilier.	Pupper)	Imaging	Specify	
Ophthalmic									
Fetal									
Abdominal									
Intraoperative									
(specify Intraoperative				<u> </u>					
Neurological									
Pediatric									
Small Organ (specify)									
Neonatal Cephalic									
Adult Cephalic									
Cardiac									
Transesophageal		-		ļ					-
Transrectal							-		
			·					-	
Transvaginal								<u> </u>	
Transurethral	-			<del> </del>	<u> </u>			<u> </u>	
Intravascular	P				-				
Peripheral Vascular									
Laparoscopic									
Musculo-skeletal									
Conventional  Musculo-skeletal		<u> </u>					-		
Superficial									
Other (specify)									
N = New indicat Additional Com			-		-			endix E	
PLEASE DO	O TON	WRIT	E BEL		IS LINE - NEEDED		JE ON A	NOTHER :	PAGE

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iLab™ Ultrasound Imaging System, 1.3 Update and Integrated Installation Option

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ber <u> </u>			·	жиашиз	® SR, 3	.2r 7(	) WILLE	
Clinical Application	A	В	M	PWD	CWD	CD	Combined (specify)	Other <sup>†</sup> (specify)
Ophthalmic								_
Fetal Imaging		X			•			
& Other*								
Cardiac, Adult								
& Pediatric								_
Peripheral								
Vessel								_

Velocity Imaging

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(Division Sign-Off)	
Division of Reproductive, Abdominal and Radiological Devices  10715/7  Diagnostic Indications for Us for the	e Form
Radiological Devices ////5// for the	
510(k) Number Atlantis® PV, 8F 15 MI	lz

Intended Use: Diag	gnostic	ultra	sound ir	naging o	of fluid flov	v analysis of t	he human b	ody as follov	WS:
					Mod Modern	e of Operation	- Golor siz		
Glinical Application	A. B	M	PWD:	CWD	Color	Amplitude.	-Velority	Committee	Other
					2000br		s imaging 2	==(Specify)=s	
Ophthalmic									
Fetal									
Abdominal									
Intraoperative (specify									
Intraoperative Neurological									
Pediatric									_
Small Organ (specify)									
Neonatal Cephalic									
Adult Cephalic									
Cardiac									
Transesophageal									
Transrectal									! !
Transvaginal									
Transurethral									
Intravascular	P								
Peripheral Vascular									
Laparoscopic						:			
Musculo-skeletal Conventional									
Musculo-skeletal Superficial									
Other (specify)									

N = New indication; P = Previously cleared by FDA; E = Added under Appendix E

Additional Comments: Cleared under K022860, November 21, 2002 and K041727 (cleared July 23, 2004) and K050684 (cleared May 20, 2005)

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Special 510(k) il ab™ Ultrasound Imaging System, 1.3 Update and Integrated Installation Option	Page	0892

Clinical Application	A	В	M	PWD	CWD	CD	Combined (specify)	Other <sup>†</sup> (specify)
Ophthalmic								
Fetal Imaging & Other*		<u>x</u>					- <del> </del>	
Cardiac, Adult & Pediatric								
Peripheral Vessel								

Intended Use: Dia	gnostic i	ıltrasç	ound im	naina af	0.110			
				taging or	fluid flov	v analysis o	f the huma	ın body as f
					20012	of Operation	Color	
Application	GANN B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Welcoty. Amaging	Combined (Specify)
Ophthalmic								
Fetal								
Abdominal								
Intraoperative		-	1					
(specify Intraoperative			-				·	1
Neurological		ļ	ļ					
Pediatric								
Small Organ (specify)		i						
Neonatal Cephalic								
Adult Cephalic								
Cardiac		-						
Transesophageal			1		-		<del>                                     </del>	
Transrectal		-		<del> </del>	-		1	
Transvaginal					<u> </u>		-	
Transurethral		_	-			<u> </u>	-	
Intravascular	E	<del> </del>						
Peripheral Vascular								
Laparoscopic		-						<u> </u>
Musculo-skeletal		+						
Conventional  Musculo-skeletal		-						
Superficial								
Other (specify)								

Special 510(k)

iLab™ Ultrasound Imaging System, 1.3 Update and Integrated Installation Option

			for the Atlantis® SR Pro, 3.2F 40 MHz									
В	М	PWD	CWD	CD	Combined (specify)	Other <sup>†</sup> (specify)						
				••••		-						
X						_						
						_						
						_						
	X X			X	X	X						

Velocity Imaging

(Division Sign-Off)

			A	tlantis®	) ICE, 9F 9	MHZ		
Intended Use: Dia	gnostic	ultras	ound i	maging	of fluid flov	w analysis of	the human	body as foll
					an constitution to the	Amplifiles	- Colur	Combine
Clinical Application	A) B	M	PAVD.	CWD	Dopplet	Dopplet	Velocity almaging	(Specity)
Ophthalmic		an advised on the				A CONTRACTOR OF THE STREET, ST		
Fetal								
Abdominal								
Intraoperative (specify								
Intraoperative Neurological								
Pediatric								
Small Organ (specify)								
Neonatal Cephalic								
Adult Cephalic								
Cardiac								
Transesophageal								
Transrectal								
Transvaginal								
Transurethral								
Intravascular	E							
Peripheral Vascular								
Laparoscopic								
Musculo-skeletal Conventional								1
Musculo-skeletal Superficial								
Other (specify)								
N = New indication  Additional Comm  (Cleared October)  PLEASE DO	ents: <u>I</u> 9,1996	Release )).	ed to m	oarket <u>A</u>	ugust 8, 200	)3 via Letter-	To-File ag	ainst K90224 
	Como		o of C		NEEDED	vias Evalus	tion (ODE	\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \
	Conc	urrenc	e 01 C	DKH, (	inice of De	evice Evalua	uen (ODE	,

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sion of Reprodui iological Devices (k) Number		12	51	Tabl		rack 1 for the s® ICE	1e	ary Table MHz			•
Clinic Appli		A	В	M	PWD	CWD	CD	Combined (specify)	Othe (specif		
Ophtl	ıalmic					*****			<del></del>		
Fetal & Oth	lmaging ier*		<u>x</u>						_		
Cardi & Ped	ac, Adult liatric										
Perip								·			
Cepha <sup>†</sup> Exa	minal, Intralic, Muscu	ilo-skele include	tal (con	vention	al), Musc	ulo-skele	tal (sup	nyroid, testes, erficial) monic Imagin			
Abdo Ceph:	minal, Intralic, Muscu	ilo-skele include	tal (con	vention	al), Musc	ulo-skele	tal (sup	erficial)			
Abdo Ceph:	minal, Intralic, Muscu	ilo-skele include	tal (con	vention	al), Musc	ulo-skele	tal (sup	erficial)			
Abdo Ceph:	minal, Intralic, Muscu	ilo-skele include	tal (con	vention	al), Musc	ulo-skele	tal (sup	erficial)		Iotion Do	
Abdo Ceph:	minal, Intralic, Muscu	ilo-skele include	tal (con	vention	al), Musc	ulo-skele	tal (sup	erficial)		Iotion Do	ppler, Col
Abdo Ceph:	minal, Intralic, Muscu	ilo-skele include	tal (con	vention	al), Musc	ulo-skele	tal (sup	erficial)	g, Tissue M	Iotion Do	ppler, Col
Abdo Ceph:	minal, Intralic, Muscumples may	ilo-skele include	tal (con	vention	al), Musc	ulo-skele	tal (sup	erficial) monic Imagin	g, Tissue M	Iotion Do	ppler, Col
Abdo Ceph:	minal, Intralic, Muscumples may	ilo-skele include g	tal (con	vention	al), Musc	ulo-skele	tal (sup	erficial)	g, Tissue M	Iotion Do	ppler, Col

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(Division Sign-Off)	·
Division of Reproductive, Abdominal and	-1
Radiological Devices 11735/	Diagnostic Indications for Use Form
510(k) Number	for the

Intended Use: Diagnostic ultrasound imaging of fluid flow analysis of the human body as follows:

Atlantis® SR Pro<sup>2</sup>, 3.2F 40 MHz

Intended Use:	Diagr	iosuc	ultra	isouna	ımagıng		OW analysis		man body a	S IOHOWS:
Clinical 22 Applications 2		В	M	PWD.	GWD	Gülür	Amplitude Doppler	Color Velosis Hmayms	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic						:				
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular		P								
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional Musculo-skeletal										
Superficial										
Other (specify)				ļ,		135.1			1:	<u> </u>

N = New indication; P = Previously cleared by FDA; E = Added under Appendix E

Additional Comments: Cleared under K050577, March 30, 2005 and K063312 (cleared November
30, 2006)
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Boston Scientific Corporation Special 510(k)

er <u> </u>	Table 5-2: Track 1 Summary Table for the Atlantis® SR Pro <sup>2</sup> , 3.2F 40 MHz										
Clinical Application	<u>A</u>	В	M	PWD	CWD	CD	Combined (specify)	Other <sup>†</sup> (specify)			
Ophthalmic				. <u> </u>			·	_			
Fetal Imaging & Other*		X				·		_			
Cardiac, Adult & Pediatric								_			
Peripheral Vessel											

† Examples may include: Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color

Cephalic, Musculo-skeletal (conventional), Musculo-skeletal (superficial)

**Velocity Imaging** 

iagnos	stic u	ltroc	, .						
		iiias	ound 1	maging	g of fluid fl	ow analysis	of the hur	nan body as	fol
						Amara	Color	Gombined	
	В	M	PWD	L CW	Dopple Dopple	Darrier			
	end balling see			ne poetarano					27.318.3
								70.00	
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		-							
				1					<del></del>
<u> </u>	P			1					
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<b>↓</b> ↓				(	1	1	1		1
							Dopple Dopple		Donler Booker Income (Specify)

Clinical Application	<u>A</u>	В	M	PWD	CWD	CD	Combined (specify)	Other <sup>†</sup> (specify)
Ophthalmic		<del></del>						
Fetal Imaging & Other*		X 						_
Cardiac, Adult & Pediatric								_
Peripheral Vessel								_